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ASSOCIATION OF DISPOSABLE DEVICE MANUFACTURERS
Providing industry views on single patient use medical devices

EVALUATION OF SAFETY AND PERFORMANCE OF REPROCESSED SINGLE-USE MEDICAL DEVICES

EXPERIENCE OF THREE MEDICAL DEVICE MANUFACTURERS:

ETHICON ENDO-SURGERY, INC.
BOSTON SCIENTIFIC CORPORATION
U.S. SURGICAL CORPORATION

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Analysis of Reprocessed Single-Use Devices
Boston Scientific Corporation

Date: January 27, 1999 (submitted to FDA)

Objective: To perform a rigorous analysis of reprocessed medical devices labeled for single use, using validated test methods and finished device specifications.

Methods: Commercially reprocessed single use biopsy forceps were obtained from hospital shelves awaiting reuse in patients. They were subjected to physical, microbiological and functional testing to determine whether or not they complied with original device specifications.

Results: Observations and/or product failures:

n=55

	Product Integrity	Foreign Material	Sterility
Biopsy Forceps			
Test 1 (n=21):	Fail (85%)	Present	Fail (4/5)
Test 2 (n=34):	Fail (57%)	Present	Fail (17/20)

Virtually all of the reprocessed devices examined were found to contain dried blood, body fluid, and/or tissue that had not been removed by the cleaning process. In addition, device integrity and functional performance failures were found to be causally related to the reprocessing procedures.

Conclusions: Reprocessed single use biopsy forceps demonstrate compromised device integrity and altered the device safety and efficacy profiles. Using such devices on more than one patient will jeopardize patient safety.

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LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviations

APIC	Association of Practitioners in Infection Control
Avg.	average
BSC	Boston Scientific Corporation
°C	degrees Centigrade
C	carbon
cc	cubic centimeter
CDC	Centers for Disease Control and Prevention
cfu	colony-forming units
CO_2	carbon dioxide
EES	Ethicon Endo-Surgery, Inc.
EtO	ethylene oxide
F	fluorine
FDA	Food and Drug Administration
H_2O_2	hydrogen peroxide
HIMA	Health Industry Manufacturers Association
in	inch(es)
lb	pound(s)
lbf	pound-force
mil	0.0254 millimeter (0.001 inch)
mm	millimeters
mmHg	millimeter of mercury
mmH_2O	millimeter of water
min	minute
N	nitrogen
No. (n)	number
O	oxygen
scc	standard cubic centimeter
SGNA	Society of Gastroenterology Nurses Associates
Si	silicon
TSB media	trypticase soy broth media
µM	microns (or micrometer)
USSC	U.S. Surgical Corporation

Summary of Key Findings of Device Integrity, Contamination, Bioburden and Performance:
Reprocessed Critical Single-Use Medical Devices

Manufacturer/ Device	Test Results			
	Product Integrity	Residual Foreign Material?	Sterility	Conformance with Performance Specifications
Ethicon Endo-Surgery				
UltraCision Coagulating Shears	**Failed.** Blemished & improperly sharpened blade, damaged tooth profile, torn clamp pad, rough alignment pin.	**Yes**	Not tested	**No.** Excessive clamp closing force; inadequate resonant frequency.
Proximate Linear Stapler	**Failed.** Incorrect product code.	**Yes**	Not tested	**No.** Excessive force needed to turn rotation knob & handle snap failed to engage.
Proximate Linear Cutters	**Failed.** Mismatched parts, cracked & loose components.	**Yes**	Not tested	**No.** Greater force-to-fire requirements.
Curved Scissors	**Passed.**	**Yes**	Not tested	**Yes.** Passed strength & scissors function testing.
Modified Allis Clamp	**Failed.** Missing part & packaging label.	**No**	Not tested	**Yes.** Passed strength testing.
Babcock Grasper	**Failed.** Missing part.	**Yes**	Not tested	**Yes.** Passed strength testing.
Multiclip Clip Applier	**Failed.** Inadequate clip count.	**Yes**	Not tested	**Yes.** Passed firing & clip forming checks.
Pneumoperitoneum Needle (PN120)	**Failed.** Mislabeled.	**Yes**	Not tested	**Yes.** Passed needle function testing.
Ultra Veress Needle (UV120)	**Failed.** Mislabeled & missing packaging label.	**Yes**	Not tested	**Yes.** Passed needle function testing.
Boston Scientific Corporation				
Biopsy Forceps (Test Series 1)	**Failed.** 85% had obvious blemishes/defects.	**Yes**	**Non-sterile** (4/5 not sterile)	**No.** Failed 'feel' test.
Biopsy Forceps (Test Series 2)	Not done	**Yes**	**Non-sterile** (17/20 not sterile)	Not tested.
U.S. Surgical Corporation				
USSC Multifire Skin Stapler	Not done	Not done	**Sterile**	**No.** Jammed after firing 10/25 remaining staples.
EES Proximate Linear Stapler	Not done	Not done	**Sterile**	**No.** Failed to fire all remaining staples.
USSC Endo Retract	Not done	Not done	**Non-sterile** (1/6 not sterile)	**Yes.**
Ethicon Metz Scissors	Not done	Not done	**Non-sterile** (1/6 not sterile)	**No.** Failure to open/close properly.
USSC Endo Clip Clip Applier	Not done	Not done	**Sterile**	**No.** Failure to fire all remaining clips.
EES Endopath EMS	Not done	Not done	**Non-sterile** (4/6 not sterile)	**Yes.**
EES Ligaclip MCA	Not done	Not done	**Sterile**	**Yes.**
USSC Multifire GIA Stapler	Not done	Not done	**Non-sterile** (2/6 not sterile)	**No.** Handle failed to return after firing
EES Endopath ETS	Not done	Not done	**Non-sterile** (2/6 not sterile)	**No.** Handle failed to return after firing.

Conclusions:

Commercial reprocessing of the critical single-use medical devices tested compromised the quality of the devices, altering the safety and effectiveness of these devices. Moreover, the use of these reprocessed disposable devices places patients at unduly high risk for nosocomial infection since the sterility of these reprocessed devices cannot be assured

1. INTRODUCTION

Reuse of medical devices labeled as single-use (or disposable) is a controversial practice that has been the focus of recent discussions concerning regulatory, legal, technical, and ethical issues. Reuse of a device labeled for use in one patient is an example of using a product in a manner that is contrary to the intended use for the device and not approved by Food and Drug Administration (FDA). Despite this, reuse of single-use devices is becoming more common in hospitals and clinics. Twenty-one percent of respondents to a survey conducted by the American Society for Healthcare Central Service Professionals indicated that their facility uses reprocessed disposable medical devices.[1] Unlike most medical practices, such reuse is strictly a cost-saving measure that offers no direct benefit to the patient.

Implicit in the growing practice of reuse of single-use devices is the perception that these devices can be cleaned and resterilized and can withstand repeated cleaning, resterilization, and use in multiple patients. Yet this change in intended use presents substantial safety risks to patients including cross-contamination, pyrogenic reaction, and device failure. Presently in the United States there are no recognized standards for reprocessing medical devices labeled for single-use, and no such standards could assure the safety of all reprocessed disposable devices. There are also no established tracking systems to record previous use(s) in particular patients of a device and/or instances of cross-contamination or other injury resulting from reuse.

FDA in a Guidance dated Sept. 24, 1987[2] concluded that any institution or practitioner who reuses a disposable medical device should be able to demonstrate the following:

- The device can be adequately cleaned and resterilized.
- The physical characteristics or quality of the device are not adversely affected by the reprocessing procedure.
- The device remains safe and effective for its intended use.

To date there has been little reliable information on the ability -- or inability -- of reprocessed single-use devices to conform to appropriate specifications concerning safety and performance. This dearth of evidence is likely related to the fact that reprocessed devices are often not labeled as such, in conjunction with a reluctance by hospitals and/or physicians to report injuries

associated with reused disposable devices for fear of lawsuits. In addition, patients are generally unaware that a reprocessed single-use device was used in their procedure and therefore unlikely to link future symptoms of infection with such reuse.

This report presents data pertaining to the cleanliness, sterility, and function of reprocessed single-use devices. Data were derived from independent evaluations of reprocessed products performed by three large manufacturers of disposable medical devices: Ethicon Endo-Surgery Inc., Boston Scientific Corporation, and U.S. Surgical Corporation.

2. OBJECTIVE

To perform a rigorous analysis of reprocessed medical devices labeled for single-use using validated test methods and finished product specifications.

3. METHODS

The determination of whether single-use medical devices meet acceptable standards for reuse was made using two general approaches. Two device manufacturers, Ethicon Endo-Surgery (EES) and Boston Scientific Corporation (BSC), collected from hospitals a representative sample of disposable devices which had been reprocessed by third-party reprocessors and which were awaiting reuse in patients. These commercially reprocessed devices were submitted to a series of rigorous evaluations by the original device manufacturer (EES or BSC) or an outside laboratory. A third medical device manufacturer, U.S. Surgical Corporation (USSC), performed in-house experiments attempting to contaminate single-use devices through simulated use in patients and then clean and resterilize these devices.

Each of the disposable devices evaluated in these investigations is categorized as critical using the classification scheme adopted by the Centers for Disease Control and Prevention[3], i.e., each was designed to be introduced into the body and come in direct contact with the bloodstream or break a mucosal barrier. Thus, the risk of infection and pyrogenic reaction is high should the device not be clean and sterile.

3.1. Evaluations Performed on Single-Use Critical Medical Devices

The above described reprocessed single-use medical devices were subjected to inspections for product integrity, evaluations of product performance, and

determinations of residual contamination (blood, body fluid, and/or tissue). Two manufacturers (BSC and USSC) also conducted sterility tests on the reprocessed disposable devices.

The medical devices tested and the actual test methods used are described for each manufacturer separately.

3.1.1. ETHICON ENDO-SURGERY (EES)

Twenty groups of nine different reprocessed EES devices were compared with EES new product release criteria to determine if the instruments met the original device specifications and in-process validation criteria. The investigations also included performance testing and visual inspections for cleanliness and product integrity. The following reprocessed EES devices were evaluated:

Electromechanical Devices

- CS/LCS UltraCision® LaparoSonic® Coagulating Shears

Mechanical Devices

- TL30, TL90, TLH90 Proximate™ Reloadable Linear Staplers (30mm and 90mm)
- TLC55 and TLC75 Proximate™ Linear Cutters (55mm and 75mm)
- DCS12 Endopath™ 5mm Curved Scissors
- BB10 Endopath™ 10mm Grasper, Babcock
- MBA10 Endopath™ Clamp, Modified Allis
- TIM20 Ligaclip™ 20/20 Multiclip Clip Applicator
- PN120 Endopath™ Needle, pneumoperitoneum (120mm)
- UV120 Endopath™ Needle, ultra Veress (120mm)

Each of the above devices is used in minimally invasive surgical procedures and is intended to come in direct contact with bodily fluids, tissue, and/or organs.

A summary of the evaluations performed for each type of reprocessed EES device is listed in Table 1. All product testing was done according to established EES protocols.

All reprocessed devices were photographed in their intact resale packages. The instruments (except for the MBA10 Endopath Modified Allis Clamp) were examined for the presence of foreign material at magnifications of up to 100X using a stereomicroscope. If no foreign material was detected on the intact device, it was then disassembled and reexamined under magnification. Any suspected proteinaceous material was examined using a polarized light microscope and tested with 10% hydrogen peroxide (H_2O_2) for analysis.[a]

[a] This latter evaluation was not performed for the CS/LCS UltraCision LaparoSonic Coagulation Shears or MBA10 Endopath Modified Allis Clamp.

Table 1. Summary of Evaluations Performed on Reprocessed EES Devices

Device Type/	Description of Evaluations	
	Product Performance	Cleanliness
CS/LCS UltraCision LaparoSonic Coagulation Shears	• Resonant frequency of blade and system • System voltage • Vibrational amplitude of blade • Clamp travel & force	• Photomicrography of teflon pad & dis-assembled instrument
TL30, TL90, TLH90 Proximate Reloadable Linear Staplers	• Force necessary to fire instrument into test skin	• Stereomicroscopic examination up to 100X • Suspected proteinaceous material tested with 10% H_2O_2 analysis
TLC55 and TLC75 Proximate Linear Cutter	• Force necessary to fire instrument into test skin	• Stereomicroscopic examination up to 100X • Suspected proteinaceous material tested with 10% H_2O_2 analysis
DCS12 Endopath 5mm Curve Scissors	• Handle strength & function • Shaft to handle retention • Shaft rotation • Cautery continuity • Scissors function • Visual inspection	• Stereomicroscopic examination up to 100X • Suspected proteinaceous material tested with 10% H_2O_2 analysis
MBA10 Endopath Clamp, Modified Allis	• Handle strength & function • Shaft to handle retention • Shaft rotation • End effector tip opening • Modified bowel allis holding force • Visual inspection	• Not done
BB10 Endopath 10mm Grasper, Babcock	• Handle strength & function • Shaft to handle retention • Ratchet handle strength • End effector tip opening • Dissectors/graspers holding force • Visual inspection	• Stereomicroscopic examination up to 100X • Suspected proteinaceous material tested with 10% H_2O_2 analysis
TIM20 20/20 Multiclip Clip Applier	• Firing checks • Clip forming checks • Visual inspection	• Stereomicroscopic examination up to 100X • Suspected proteinaceous material tested with 10% H_2O_2 analysis
PN120 Endopath Needle, Pneumoperitoneum, 150mm	• Stylet opening & function • Flow rate • Visual inspection	• Stereomicroscopic examination up to 100X • Suspected proteinaceous material tested with 10% H_2O_2 analysis
UV120 Endopath Needle, ultra Veress, 120mm	• Stylet opening & function • Needle penetration • Flow rate • CO_2 leak rate • Visual inspection	• Stereomicroscopic examination up to 100X • Suspected proteinaceous material tested with 10% H_2O_2 analysis

3.1.2. BOSTON SCIENTIFIC CORPORATION (BSC)

Reprocessed single-use BSC devices were subjected to a number of tests to determine if they met recognized standards for cleanliness and sterility. The majority of the devices had been reprocessed by third party reprocessers. The other devices were not labeled to indicate whether they were reprocessed at

the hospital or by a commercial reprocessor. All devices were retrieved from hospitals and medical centers where they were awaiting reuse in patients.

Two separate series of investigations were performed by BSC. The first was presented at a Joint Association for the Advancement of Medical Instrumentation/U.S. FDA conference on *Reprocessing Medical Devices: Designing, Testing and Labeling* held November 5-7, 1997 in Dallas Texas. For this investigation, tests for bioburden/sterility, pathological examination, and functionality were performed on a total of 21 commercially reprocessed Microvasive™ single-use biopsy forceps that were labeled 'sterile'. Testing of these 21 devices consisted of the following:

- **Sterility/bioburden testing.** Five samples were sent to a contract laboratory for bioburden residue/sterility testing.

- **Pathologic examination**. Three samples were analyzed destructively for contamination by a contract laboratory. Areas with visual contamination were subsequently subjected to pathologic determination.

- **Performance and functionality testing**. The remaining 13 reprocessed single-use biopsy forceps, nine of which were supplied with an outside jacket, underwent six evaluations of performance/function (handle pull, pull test, loop test, ring gauge, cutter engage, and rotation test). In addition, a visual inspection of each of the 13 reprocessed devices was conducted, noting the appearance of any kinks or disruptions/anomalies in the integrity of the product surface or jacket.

  The second series of investigations performed on reprocessed single-use devices by BSC consisted of the following tests.

- **Luminol method for determination of residual blood.** Fourteen biopsy forceps samples (including seven Radial Jaw 3 forceps) were tested for the presence of residual blood. Each device labeled clean and ready for use was cut open and sprayed with luminol compound to expose any remaining contamination. Luminol is an organic compound that emits a visible greenish light with a peroxidase-like activity when placed in contact with hemoglobin.

- **Electron microscopy and microprobe analysis.** The topography of the material surface and surface configuration of any residual contamination

on seven additional reprocessed biopsy forceps were assessed microscopically using an electron microscope. The following locations were examined on each forceps: coilspring, 10 and 400 mm above the tip; wire, 100 and 300 mm above the tip; and coilspring, welding area, 200 mm above the tip.

In addition, a sectional spectrum analysis of the concentration of carbon, oxygen, silicon, nitrogen, and fluorine on the surface of coil and pull wires approximately 10 mm above the tip of each of the reprocessed biopsy forceps was performed. A homogeneous distribution of the elements was assumed for the element quantification. A similar analysis was performed on a newly manufactured, unused biopsy forceps to serve as a control.

- **Sterility/bioburden testing.** A standard microbiological bioburden test was performed on another subset of reprocessed biopsy forceps retrieved from hospitals. A total of 20 devices labeled 'sterile' was evaluated. The bioburden method requires the devices to be aseptically cut into small pieces that are put into a sterile solution for agitation and then placed in contact with bacterial growth medium for enumeration of any contaminating organisms.

3.1.3. U.S. SURGICAL CORPORATION (USSC)

USSC performed in-house laboratory experiments in which instruments labeled for single use were intentionally contaminated with foreign material and bacteria to simulate use in patients, subjected to standard hospital cleaning and sterilization procedures, and subsequently evaluated for sterility and functional performance.

Six samples of each of the following single-use devices were tested.

- USSC Multifire Premium 35 Disposable Skin Stapler and EES Proximate Plus Skin Stapler
- USSC Auto Suture Endo Retract Maxi and Ethicon Endopath Metz Scissors with Unipolar Cautery and Rotating Shaft
- USSC Auto Suture Endo Clip Disposable Clip Applicator, EES Endopath EMS Endoscopic Multifeed Stapler and EES Ligaclip MCA Multiple Clip Applier

- USSC Multifire Endo GIA 30 Disposable Stapler and EES Endopath ETS Endoscopic Linear Cutter.

Each of these devices is intended for use in minimally invasive surgical procedures and all are introduced directly into the body.

The following general procedure was followed for each device. Instrument tips were immersed into British Soil[b] inoculated with 1.51×10^6 *Bacillus subtilis* spores per mL. Clips or staples were fired into the inoculum; the Endo Retract Maxi and Ethicon Metz Scissors were maneuvered in the inoculum. Instruments were then placed in a bin, covered, and allowed to dry for over 48 hours. They were placed into an ultrasonic bath containing enzymatic cleaner (Terga-zyme) for 15 minutes a total of three times, then brushed with a soft brush and rinsed thoroughly with water. Each of the cleaned instruments was sealed inside breather pouches and processed through an ethylene oxide (EtO) hospital sterilization hot cycle with two hours of exposure.

Following the sterilization cycle, remaining staples from each USSC Multifire Premium and EES Proximate Skin Stapler, and remaining clips from each USSC Endo Clip, EES Endopath EMS and Ligaclip MCA Clip Applier, were fired into bottles of TSB media and incubated for seven days at 30 to 35 °C. Each of the cleaned and processed USSC Endo Retract Maxi, Ethicon Metz Scissors, USSC Multifire Endo GIA Stapler, and EES Endopath ETS Linear Cutter was swirled in bottles of TSB media and incubated for seven days at 30 to 35 °C.

Following the seven-day incubation interval, instruments (or clips or staples) were tested for the presence of the indicator organism (*B. subtilis*).

All instruments were evaluated for functionality following cleaning and sterilization (and after sterility testing in case of Endo Retract Maxi, Metz Scissors, Multifire Endo GIA Stapler, and Endopath ETS Linear Cutter).

[b] Containing 100 mL fetal bovine serum, 10 mL 0.45% saline solution, 5.5 g dried powder milk, and 27.3 mL sheep's blood.

4. RESULTS

Comprehensive reports detailing results (as well as the methodology used) of the product testing performed by EES, BSC, and USSC are available upon request.

4.1. Assessment of Residual Contamination

In their evaluations, EES and BSC assessed the presence of foreign material on samples of previously used and commercially reprocessed single-use medical devices. Of the devices tested by EES, evidence of contamination with residual blood, body fluids, and/or tissue was found in 12 (92%) of the 13 reprocessed devices. These devices were labeled 'clean and sterile'. In some cases foreign matter was found in areas of the device not exposed normally to tissue, suggesting that the residual matter was transferred during use or during the cleaning process. In one case the residue present on an internal component of an LCS UltraCision Coagulating Shears device had the potential to interfere with EtO passage during the resterilization procedure.

Of the devices tested by BSC, residual blood was found in 8 (57%) of the 14 reprocessed biopsy forceps tested using the luminol method, and visible contamination was evident for 29 (83%) of the 35 evaluations of reprocessed biopsy forceps using electron microscopy. Trace element analysis indicated increased concentrations of carbon and nitrogen on reprocessed biopsy forceps, which is consistent with the presence of proteinaceous material. Each of the reprocessed biopsy forceps evaluated by BSC was certified by the reprocessor to be 'clean and sterile', and was awaiting reuse at hospitals and medical clinics.

Results of testing for residual contamination by EES and BSC are summarized separately below. Similar evaluations were not part of the in-house laboratory investigation conducted by USSC.

4.1.1. EES EVALUATIONS

Blood and/or tissue was present on 12 of the 13 commercially reprocessed, EES single-use devices examined microscopically for the presence of proteinaceous material. Each of the devices was certified to be clean and sterile by the commercial reprocessor. Table 2 summarizes the results of these investigations.

Table 2. Examination for Presence of Residual Blood, Body Fluid, and/or Tissue on Previously Used, Reprocessed Disposable Medical Devices
EES Investigations

Device	Results of Microscopic Inspection
CS UltraCision Coagulating Shears	Residue found on internal bushing, clamp arm, and clamp pad.
LCS UltraCision Coagulating Shears	Residue found on handle, linkage arm, LCS shaft, and internal bushing.
TLC55 Proximate Linear Cutter	Residual proteinaceous material found adjacent to proximal end of anvil and on some internal plastic parts. Rust present on many internal metal surfaces, particularly near anvil.
TLC55 Proximate Linear Cutter	Flake of residual proteinaceous material found on metal tab on knife side.
TLC75 Proximate Linear Cutter	Significant deposit of residual proteinaceous material found at distal end of anvil.
TL90 Proximate Linear Stapler	Flake of residual proteinaceous material found in groove where one driver meets the staple.
TLH90 Proximate Linear Stapler	Proteinaceous deposit found in back of anvil assembly.
DCS12 Curved Scissors	Flake of dried blood found on scissors blade.
BB10 Babcock Grasper	Residual proteinaceous material on indented screws near clamp end.
MBA10 Modified Allis Clamp	No residual proteinaceous material found.
TIM20 20/20 Multiclip Clip Applier	Residual proteinaceous deposit found on the cartridge and in a recessed hole near the tip of the handle.
PN120 needle[a]	Residual blood found on outside of stopcock assembly.
UV120 Veress needle	Small flakes of residual dried blood found between sections of metal tube.

[a] Device mislabeled as UV120 ultra Veress needle.

4.1.2. BSC EVALUATIONS

Contamination with residual blood was found on 8 (57%) of the 14 commercially reprocessed BSC biopsy forceps evaluated using the luminol method. Luminescence was observed at the wire 10 mm above the tip in five of the seven reprocessed biopsy forceps; luminescence ranged from 1.4% to 5.0% at this location [contamination with 1 mL blood dilution yields 100% luminescence]. Similarly, visible contamination was apparent along the inner surface of the inner plastic tube, approximately 100 mm above the tip in three of the seven samples tested; luminescence in these devices ranged from 1.7% to 10.6%.

The presence of visible contamination on reprocessed BSC biopsy forceps was evaluated using electron microscopy (10 and 100 μM) at five different locations [coilspring, 10 and 400 mm above tip; wire, 100 and 300 mm above tip; coilspring welding area, 200 mm above tip]. The evaluation started on the

distal tip and progressed upwards towards the proximal end to determine the length of contamination. A total of seven different reprocessed biopsy forceps were tested. Of the 35 microscopic evaluations performed, 29 (83%) yielded visible contamination. No visible contamination was evident for four of the devices at the coilspring, approximately 400 mm above the tip, and for two of the devices at the welding area, approximately 200 mm above the tip. By comparison, each of the seven reprocessed biopsy forceps had visible contamination at the coilspring area, 10 mm above the tip and along the wire, 100 mm and 300 mm above the tip.

The seven remaining soiled and reprocessed BSC biopsy forceps were subjected to trace element analysis at the surface of wire, approximately 10 mm above the tip. The results of this analysis, summarized in Table 3, indicate an increase in the concentrations of carbon and nitrogen, constituents of peptide chains. A decrease in silicon concentration was also apparent and is interpreted to reflect an effect of the additional contamination layer and/or removal of silicon as a result of use or the cleaning process.

Table 3. Results of Trace Element Analysis (% Concentration) on Soiled & Reprocessed Single-Use Biopsy Forceps Manufactured by BSC

Element	Control Device	Reprocessed Devices	
		Median	Range
Carbon	58%	78%	66 - 83%
Oxygen	23%	17%	14 - 25%
Nitrogen	< 0.1%	2.1%	1 - 5%
Silicon	19%	2%	0.8% - 3%
Fluorine	< 0.1%	< 0.1%	0.1%

In a separate series of investigations, three soiled and reprocessed BSC biopsy forceps were analyzed destructively for residual contamination. Several areas of visual contamination were evident for two of the three reprocessed single-use devices. Subsequent pathologic identification of the contamination indicated that the residual material on these cleaned and sterilized devices was, in fact, blood.

4.2. Sterility Testing

Bioburden residue/sterility testing was performed by BSC on commercially reprocessed biopsy forceps. USSC performed standard hospital cleaning and EtO resterilization procedures in-house on soiled disposable devices. Each of the medical devices tested in these evaluations is categorized as a critical use

device that must be sterile before use since the risk of infection if microbial contamination is present is high.

A significant percentage of the reprocessed devices evaluated for bioburden/sterility was found to be non-sterile. In BSC's evaluations, 85% of the commercially reprocessed biopsy forceps in one investigation, and 80% in a second investigation, were found to be non-sterile. In USSC's experiments, 19% of the devices intentionally contaminated with *B. subtilis* tested positive for this organism following a standard hospital cleaning and resterilization procedure.

4.2.1. BSC EVALUATIONS

In the first BSC investigation, four (80%) of five reprocessed biopsy forceps submitted for bioburden/sterility testing were found to be non-sterile. Contaminating organisms were identified as *Stapylococcus* and *Corynebacterium* species.

In the second investigation, bioburden/sterility testing was performed on 20 commercially reprocessed biopsy forceps. Seventeen (85%) of the 20 devices tested did not meet the requirements for sterility. Bioburden estimates ranged from <50 to 4,600 cfu/device and the contaminating organisms were identified as aerobic spore-forming *Bacillus* species, gram-positive *Streptococci* and *Micrococci* species, and gram-negative *Pseudomonas* species.

4.2.2. USSC EVALUATIONS

In USSC investigations, a total of 54 single-use, sterile medical devices were intentionally contaminated with *B. subtilis* (nine different device types), subsequently exposed to a standard hospital cleaning and EtO sterilization procedures, and then tested for bioburden/sterility. Of the 54 devices subjected to this experimental protocol, 10 (19%) tested positive for *B. subtilis* following cleaning/resterilization (Table 4).

Table 4. Results of Sterility Testing of Reprocessed Single-Use Medical Devices by USSC

Device Type	No. Contaminated/ Resterilized/Tested	No. Positive for *B. subtilis*
USSC Multifire Premium 35 Skin Stapler	6	0
EES Proximate Linear Stapler	6	0
USSC Endo Retract Maxi	6	1
Ethicon Metz Scissors	6	1
USSC Endo Clip Clip Applicator	6	0
EES Endopath EMS	6	4
EES Ligaclip MCA	6	0
USSC Multifire Endo GIA 30 Stapler	6	2
EES Endopath ETS	6	2
TOTAL	**54**	**10**

4.3. Evaluations of Physical Integrity, Product Performance and Function

4.3.1. EES EVALUATIONS

A total of 20 soiled and reprocessed single-use medical devices were examined visually for obvious signs of damage and underwent testing to determine if the devices continued to meet original EES product performance specifications. Results of these evaluations are discussed separately for each of the nine different types of devices assessed.

In general, evaluations indicated that the previously used electromechanical UltraCision devices failed to meet product performance specifications following cleaning and resterilization. These reprocessed instruments also exhibited damaged parts. Previously used mechanical Proximate Linear Cutters also failed to meet original product specifications concerning force-to-fire after cleaning and resterilization. While the remaining reprocessed mechanical devices generally passed strength and functional testing, they failed to conform with EES acceptance standards for quality (i.e., mismatched, missing, or damaged parts). Many of the reprocessed mechanical devices also were in noncompliance with FDA Good Manufacturing Practices for Medical Devices (mislabeled product, missing packaging label).

<u>CS/LCS UltraCision LaparoSonic Coagulating Shears</u>

The UltraCision LaparoSonic Coagulating Shears are primarily indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to, or substitute for,

electrosurgery, lasers or steel scalpels in abdominal, pediatric, gynecologic, and other endoscopic procedures. Visual inspection of four reprocessed CS and LCS UltraCision devices indicated several areas of product damage, as summarized below. Each would have been classified by EES as a nonconformance and would have resulted in the product failing to meet release specifications for sale.

- **Blade**. The reprocessed blade on the CS UltraCision device had been sharpened, creating a change to the sound wave form that could potentially cause the blade to fracture and/or shatter during a procedure. The blade on the reprocessed LCS device had an obviously damaged region, also resulting in the potential for fracture during a surgical procedure.

- **Clamp Pad.** There was damage to the tooth profile of the reprocessed CS and LCS UltraCision devices. Teeth of the clamp pad are used to grip tissue during the cut or coagulation mode. An inability to adequately contain the tissue during a procedure would result in less than optimal product performance, including the inability to complete an incision or to coagulate. In addition, the clamp pad on one reprocessed CS UltraCision device was partially torn from the clamp arm, also causing the potential for inadequate tissue containment during a procedure.

- **Alignment Pin.** The plastic holder for the alignment pin of the reprocessed CS UltraCision device had rough edges and excessive flash. These burrs and irregular surface have the potential to tear a latex glove during a surgical procedure, violating the sterile field. The alignment feature (i.e., pin) was missing from the reprocessed LCS UltraCision device. Without proper alignment the instrument will not function.

Functional characteristic tests were performed on the four reprocessed UltraCision devices. Results of these tests are summarized in Table 5. In one series of tests of two devices, the reprocessed devices failed to conform to original EES specifications regarding clamp-closing force; the clamp-closing force for both reprocessed devices was greater than EES acceptance criteria. Similarly, tests of two additional UltraCision devices indicated nonconformance in system resonant frequency, where values for both reprocessed devices were lower than EES acceptance criteria.

Table 5. Results of Product Tests on Reprocessed CS/LCS UltraCision LaparoSonic Coagulating Shears

Reprocessor/ Device Number	EES Product Function Tests[a]				
	Resonant Freq. (blade) (55,100 ± 400 Hz)	Resonant Freq. (system) (55,500 + 300 Hz & -200 Hz)	System Voltage (<165 VDC @ 400 mA)	Vibrational Amplitude of Blade (85 ± 15 microns peak to peak)	Clamp Travel/Force[b] (Thumb level closing force <0.5 lb)
Orris					
LCS Handset #1	55,289 [P]	55,284 [F]	88 [P]	69.7 [F]	0.4 [P]
LCS Handset #2	55,290 [P]	55,276 [F]	90 [P]	74.4 [P]	N/A
Applied Medical Technologies					
CS Handset #1	55,516 [P]	55,500 [P]	74 [P]	70.4 [P]	0.58 [F]
CS Handset #2	55,509 [P]	55,499 [P]	85 [P]	75.7 [P]	N/A

[a] EES product acceptance criteria for each test shown in parentheses.
[b] Electrical measurements performed on the reprocessed CS and LCS devices required two EES production samples, while mechanical measurements (clamp travel/force) required only one measurement according to EES performance specifications.
P = reprocessed device met EES performance specifications for test.
F = reprocessed device failed to meet EES performance specifications for test.

TL30, TL90 and TLH90 Proximate Reloadable Linear Stapler

The Proximate Reloadable Linear Stapler has application throughout the alimentary tract and in thoracic surgery for transection and resection of internal tissues. Three reprocessed Proximate Linear Staplers were subjected to visual inspection for product integrity and to a test of the force necessary to fire the instrument into a test skin model. Visual inspection revealed that the product code on one of the reprocessed linear staplers was incorrect; a reprocessed TLH90 device was mislabeled as a TPH90 model, the latter of which is an invalid product code.

During functional testing of these reprocessed devices, the handle snap on the reprocessed TL90 instrument failed to engage as a result of a short cross-head stroke. This is an obvious functional nonconformance. Excessive force was necessary to turn the rotation knob on the TLH90 device, resulting in a greater load at maximum staple formation relative to a control linear stapler (Table 6). This latter defect would have violated EES product acceptance criteria which requires that the adjusting knob on the TLH90 product rotate smoothly, not be difficult to turn, and hold its position.

Table 6. Summary of Force-to-Fire Performance Tests of TL30, TL90, and TLH90 Proximate Reloadable Linear Staplers

Device	Maximum Load (lbf)	Load at Maximum Staple Formation (lbf)
Control TL90	**40.875**	**24.475**
Reprocessed TL90[a]	30.649	25.220
	39.747	28.180
Reprocessed TL30	20.791	9.405
Reprocessed TLH90	48.092	42.137

[a] Two tests performed on same reprocessed device.

TLC55 and TLC75 Proximate Linear Cutters

EES's Proximate Linear Cutters are used in gastrointestinal, gynecologic, thoracic, and pediatric surgery for transection, resection, and the creation of anastomoses. Three reprocessed Proximate Linear Cutters were evaluated, two TLC55 models and one TLC75 model. Visual inspection revealed that the serial number for the anvil half differed from that for the knife half for both of the reprocessed TLC55 models. These devices are composed of two major interfacing assemblies that come together to form the handle; during manufacturing, identical batch numbers are stamped into the handle halves to assure compatibility. Mismatched parts have the potential to result in gross staple malformation. The reprocessed TLC75 Proximate Linear Cutter had a loose plastic plug at the distal end of the anvil that was easily removed. Large cracks were also seen in some of the plastic parts, including the plug and parts near the knife. The presence of such cracks could affect the performance of the instrument.

Each of the reprocessed devices was fired into a test skin and the force necessary to fire the instruments was measured; tests were repeated twice for each instrument. For comparison purposes, similar tests with an unused TLC55 and TLC75 device were also performed. Results are shown in Table 7.

Table 7. Summary of Force-to-Fire Performance Tests of TLC55 and TLC75 Proximate Linear Cutters

Device	Test No.	Avg. Load during Ramp Up (lb)	Total Energy (Ramp Up) (lbf-in)	Avg. Load during Staple Formation (lb)	Total Energy (Staple Formation) (lbf-in)
Control TLC75	**1**	**5.214**	**1.412**	**8.047**	**20.219**
Reprocessed TLC75	1	5.462	1.320	9.120	21.851
	2	5.827	1.578	8.975	20.494
Control TLC55	**1**	**5.766**	**1.610**	**8.658**	**14.899**
	2	**6.515**	**2.172**	**8.625**	**15.705**
Reprocessed TLC55A	1	6.593	2.088	10.568	17.833
	2	5.810	2.010	11.428	20.143
Reprocessed TLC55B	1	4.509	1.559	9.025	15.343
	2	4.511	1.541	8.961	15.606

These tests indicate that the average load during staple formation, as well as the total energy expended during staple formation, was greater for the reprocessed linear cutters than for control devices. Maximum load was also higher for the reprocessed TLC75 (13.107 and 11.793 lbf) device compared to its control (11.077 lbf); a similar observation was made for the reprocessed TLC55 devices (range: 13.351 to 16.732 lbf in four tests) compared to their controls (12.363 and 13.017 lbf). The greater force-to-fire could result in surgeons experiencing difficulty firing these linear cutters, leading to incomplete staple formation with resultant poor hemostasis.

DCS12 Endopath 5mm Curved Scissors

One commercially reprocessed DCS12 Endopath 5mm Curved Scissors instrument was subjected to a visual inspection and performance evaluation. The curved scissors is used to facilitate grasping, mobilization, dissection, and transection of tissue. The instrument passed the criteria for blemishes, product integrity, and identification (legible logo and production number). It also met EES product specifications for handle compression strength (did not break under 7.5 lbs of compressive force), tensile strength (did not break under 5 lbs tension), handle function (did not bind and opened/closed freely), shaft rotation (rotated through 360+ degrees in either direction with minimal resistance), shaft detent positions (shaft indexed to detents when rotated), cautery (continuity between tip and cautery pin = 1.2 ohms), and scissors function (cut freely through both layers of dental dam on first actuation).

MBA10 Endopath Modified Allis Clamp

The MBA10 Endopath Modified Allis Clamp, like the curved scissors, is primarily used to facilitate grasping, mobilization, dissection, and transection of tissue. Visual inspection of a single reprocessed instrument revealed that the protective PVC tips on the end effectors were missing; this could result in the device losing its sterility if the package is torn during shipping and handling. In addition, the original device packaging label was missing so that instructions for use, warnings, precautions, or contraindications were not provided with the reprocessed instrument.

The reprocessed MBA10 Modified Allis Clamp met EES' acceptance criteria for blemishes, handle compression strength (did not break under 15 lb of compression), handle tensile strength (did not break under 5 lb tension), handle function (did not bind, opened and closed freely), shaft-to-handle retention (shaft held to handle under sustained tensile pressure of 25 lb pull-out force), holding force (capable of grasping 0.248 in diameter gauge pin, and lifting 5 lb weight with pin vertically positioned in the circular section), shaft detent position (shaft indexed to detent when rotated through 360° in either direction), and end effector tip opening (19.2 mm).

BB10 Endopath 10 mm Babcock Grasper

The BB10 Endopath 10 mm Babcock Grasper is used to facilitate grasping, lifting, and retraction of tissue; it is contraindicated for use in procedures involving lung tissue. Visual inspection of a single reprocessed instrument revealed that the protective PVC tips on the end effectors were missing. This nonconformance with original product specifications could result in the device losing its sterility if the package is torn during shipping and handling. The reprocessed product also failed EES's functional criterion for motion of the shaft detents when rotated through 360° in either direction; specifically, the motion was too stiff and erratic for proper operation.

The reprocessed Babcock Grasper passed EES criteria for blemishes, product identification, handle compression strength (did not break under 15 lb of compression), handle tensile strength (did not break under 5 lb tension), handle function (did not bind, opened and closed freely), shaft-to-handle retention (shaft held to handle under sustained tensile pressure of 25 lb pull-out force), holding force (capable of grasping 1 lb using 7 mil dental dam material overlaid with 5 mil polyethylene on both sides), ratchet handle

strength (held 15 lb force when engaged), and end effector tip opening (29.4 mm).

TIM20 Ligaclip 20/20 Multiclip Clip Applier

The Ligaclip Multiclip Clip Applier is used on vessels or other tubular structures wherever a nonabsorbable ligating clip is indicated. The single reprocessed instrument met EES' acceptance criteria for blemishes, product integrity, and identification. Performance testing focused on common firing and clip forming checks. During firing, the reprocessed device operated satisfactorily, and there was no visual seam separation. The firing mechanism fully functioned when actuated, and the clip did not stick to the tracks of the clip applier during actuation.

The reprocessed device failed to meet EES' acceptance criteria for proper clip count, containing 19 instead of 20 clips.

PN120 Endopath Needle, pneumoperitoneum, 150 mm

The PN120 Endopath Needle is designed to establish pneumoperitoneum in gynecologic laparoscopy and other minimally invasive abdominal procedures. Inspection of the single reprocessed product indicated that it was mislabeled. The package of the reprocessed device listed it as a UV120 Veress Needle, rather than a Pneumoneedle, product code PN120. This major defect could cause significant injury or illness to the patient or surgeon as the indication that the needle tip will not be exposed for abdominal penetration is different in UV120 compared to PN120 and is a violation of 820.10 of the Current Good Manufacturing Practices for Medical Devices.

The single reprocessed PN120 Pneumoneedle met EES' acceptance criteria for stylet opening (not occluded in static position), stylet function (red indicator shows in compressed but not static state), air flow rate (>1284 cc/min @ 17 mmHg), and leak rate (< 200 cc/min @ 20 mmHg).

UV120 Endopath Needle, ultra Veress, 120 mm

The UV120 Endopath Needle, Ultra Veress is designed to establish pneumoperitoneum in gynecologic laparoscopy and other minimally invasive abdominal procedures. Two reprocessed devices were evaluated; both were subjected to visual inspection and one was additionally subjected to performance testing. Visual inspection revealed that one of the reprocessed

needles was mislabeled. The package of the reprocessed device listed it as a UV120 Veress Needle although it was actually a Pneumoneedle (see above), product code PN120 and included a stopcock assembly. This major defect could cause significant injury or illness to the patient or surgeon as the indication that the needle tip will not be exposed for abdominal penetration is different in PN120 compared to UV120 and is a violation of 820.10 of the Current Good Manufacturing Practices for Medical Devices.

The packaging for the other reprocessed needles did not include instructions for use, warnings, precautions, or contraindications, also violating FDA's Current Good Manufacturing Practices for Medical Devices.

Functional testing of the single reprocessed UV120 Needle indicated that the device met EES' performance criteria for stylet opening (not occluded in static position), stylet function (pink in compressed state, green in static state), CO_2 flow rate (>185 scc/min @26 mmH_2O), and CO_2 leak rate (0 cc/min at 272 mm H_2O). The force necessary to penetrate 2.0 mil polyethylene film and the spring force needed to deflect the stylet were higher for the reprocessed device than for an unused UV120 Needle. Specifically, the recorded force to penetrate was 0.704 lb for the reprocessed device compared to 0.657 lb for the original EES instrument; the spring force to deflect the stylet for the two devices was 0.52 lb compared to 0.43 lb, respectively.

4.3.2. BSC EVALUATIONS

Thirteen reprocessed Microvasive biopsy forceps were subjected to performance testing. Visual inspection of these 13 reprocessed devices revealed the following defects: a curve in the coil (n=5), gaps in the cutters (n=2), visible corrosion (n=2), scratches (n=1), and a chip on the needle (n=1). Only two (15%) of the reprocessed devices were free of any obvious blemish or defect.

Each of the 13 reprocessed devices met BSC's acceptance criteria for the following evaluations: handle pull, pull test, loop test, ring gage, cutter engage, and rotation test. The nine reprocessed devices that were jacketed were subjected to an additional feel test. Only four of these nine passed this test. Four of the reprocessed jacketed biopsy forceps had nicks and one had two perforations. Defects on these five (55%) devices would have resulted in the device being rejected by BSC standards.

4.3.3. USSC EVALUATIONS

Each of the 54 disposable devices was subjected to functional testing following reprocessing. Of the 54 reprocessed devices tested, 14 (26%) failed to function properly, as shown in Table 8. Specific performance failures noted included an inability to fire properly, to fire the appropriate number of staples/clips, to close after firing, and to open and close (Metz Scissors).

Table 8. Summary of Functional Performance of Reprocessed Single-Use Medical Devices by USSC

Device Type	No. Evaluated	No. Failed Functional Testing	Nature of Performance Failure
USSC Multifire Skin Stapler	6	1	Jammed after 10 of remaining 25 staples fired.
EES Proximate Plus Skin Stapler	6	2	One instrument fired only 4 of remaining 15 staples; the other fired only 1 of remaining 15 staples.
USSC Auto Suture Endo Retract Maxi	6	0	None detected.
Ethicon Endopath Metz Scissors	6	1	Failure to open/close shears.
USSC Endo Clip Clip Applicator	6	3	One instrument had only 2 of remaining 10 clips fire; two others had only 3 of remaining 10 clips fire.
EES EMS Endoscopic Multifeed Stapler	6	0	None detected.
EES Ligaclip Multiclip Clip Applier	6	0	None detected.
USSC Multifire Endo GIA Stapler	6	1	Handle failed to return after firing.
EES ETS Linear Cutter	6	6	All six instruments had handle fail to return after firing.
TOTAL	**54**	**14**	

5. DISCUSSION

The design of medical devices, particularly those which are introduced into the body and come in direct contact with the bloodstream or other parts of the body or break the mucosal barrier (i.e., devices classified as critical) must be compatible with cleaning and decontamination protocols. Devices that do not allow unobstructed access to surfaces for cleaning, such as those with long and/or small diameter lumens, rough or textured surfaces, or constructed with hinges or other features that can interfere with cleaning, are generally not

suitable for reuse. Moreover, medical devices that cannot be cleaned and/or resterilized without altering the device's physical integrity and function are not suitable for reuse.

New developments in the electronic, plastic, metallurgy, and ceramics industries, coupled with progress in design engineering and advances in our understanding of normal physiologic and disease processes, has resulted in the introduction of a wide variety of sophisticated devices to assist in the diagnosis and treatment of disease. Many of the newer, sophisticated medical devices available to healthcare practitioners today are not suitable for reuse. The complex, delicate design of certain single-use devices is not sufficiently durable to withstand repeated use, cleaning, and resterilization. In some cases, the intricate construction of disposable medical devices does not permit ready access to all surfaces and thus these devices cannot be reliably cleaned and resterilized after use.

In addition, the material composition of many single-use medical devices is incompatible with sterilization methods available to healthcare organizations and commercial reprocessors. For example, steam is recognized by the Centers for Disease Prevention and Control, APIC (Association for Practitioners in Infection Control), and SGNA (Society of Gastroenterology Nurses and Associates) as the only effective means of sterilizing a used device, since the high temperature will destroy any residual organisms remaining after cleaning. The high polymeric material content of many single-use devices, however, makes them unsuitable for steam sterilization methods. While low-temperature sterilization methods are available (i.e., EtO gas sterilization, hydrogen peroxide), they cannot provide adequate sterility assurance for many delicate instruments and are unable to efficiently kill the living organisms left from inadequate cleaning.

For these reasons, certain medical devices are labeled as single-use instruments, intended for the benefit of just one patient and should not be reused. Healthcare facilities are increasingly turning to such reuse for cost-containment purposes. Presently, companies engaged in the reprocessing (cleaning, resterilizing, and repackaging) of single-use medical devices (i.e., commercial reprocessors) in the United States are not subject to the same regulatory requirements as original device manufacturers. Specifically, third party commercial reprocessors are not required to demonstrate that: 1) reprocessed devices can withstand the rigors of reuse, 2) the physical

characteristics of the device are not adversely altered by the reprocessing procedure, and 3) the device can undergo validated cleaning and resterilization procedures.

Several medical device manufacturers and professional organizations (e.g., Health Industry Manufacturers Association, HIMA) have petitioned FDA to require third-party commercial reprocessors to comply with existing regulations governing medical device manufacturing, specifically 510(k) and PMA regulations. In response, FDA has requested data demonstrating adverse consequences arising from the reprocessing of single-use medical devices.

Accordingly, EES, BSC, and USSC conducted this series of investigations designed to rigorously evaluate the cleanliness, sterility, and performance of reprocessed single-use devices. Key findings of these investigations related to product integrity and performance, contamination with residual blood, body fluid, and/or tissue, and bioburden/sterility testing are summarized in Table 9.

Table 9. Summary of Key Findings of Device Integrity, Contamination, Bioburden and Performance: Reprocessed Critical Single-Use Medical Devices

Manufacturer/ Device	Test Results			
	Product Integrity	Residual Foreign Material?	Sterility	Conformance with Performance Specifications
Ethicon Endo-Surgery				
UltraCision Coagulating Shears	**Failed.** Blemished & improperly sharpened blade, damaged tooth profile, torn clamp pad, rough alignment pin.	**Yes**	Not tested	**No.** Excessive clamp closing force; inadequate resonant frequency.
Proximate Linear Stapler	**Failed.** Incorrect product code.	**Yes**	Not tested	**No.** Excessive force needed to turn rotation knob & handle snap failed to engage.
Proximate Linear Cutters	**Failed.** Mismatched parts, cracked & loose components.	**Yes**	Not tested	**No.** Greater force-to-fire requirements.
Curved Scissors	**Passed.**	**Yes**	Not tested	**Yes.** Passed strength & scissors function testing.
Modified Allis Clamp	**Failed.** Missing part & packaging label.	**No**	Not tested	**Yes.** Passed strength testing.
Babcock Grasper	**Failed.** Missing part.	**Yes**	Not tested	**Yes.** Passed strength testing.
Multiclip Clip Applier	**Failed.** Inadequate clip count.	**Yes**	Not tested	**Yes.** Passed firing & clip forming checks.
Pneumoperitoneum Needle (PN120)	**Failed.** Mislabeled.	**Yes**	Not tested	**Yes.** Passed needle function testing.
Ultra Veress Needle (UV120)	**Failed.** Mislabeled & missing packaging label.	**Yes**	Not tested	**Yes.** Passed needle function testing.
Boston Scientific Corporation				
Biopsy Forceps (Test Series 1)	**Failed.** 85% had obvious blemishes/ defects.	**Yes**	**Non-sterile** (4/5 not sterile)	**No.** Failed 'feel' test.
Biopsy Forceps (Test Series 2)	Not done	**Yes**	**Non-sterile** (17/20 not sterile)	Not tested.
U.S. Surgical Corporation				
USSC Multifire Skin Stapler	Not done	Not done	**Sterile**	**No.** Jammed after firing 10/25 remaining staples.
EES Proximate Linear Stapler	Not done	Not done	**Sterile**	**No.** Failed to fire all remaining staples.
USSC Endo Retract	Not done	Not done	**Non-sterile** (1/6 not sterile)	**Yes.**
Ethicon Metz Scissors	Not done	Not done	**Non-sterile** (1/6 not sterile)	**No.** Failure to open/close properly.
USSC Endo Clip Clip Applier	Not done	Not done	**Sterile**	**No.** Failure to fire all remaining clips.
EES Endopath EMS	Not done	Not done	**Non-sterile** (4/6 not sterile)	**Yes.**
EES Ligaclip MCA	Not done	Not done	**Sterile**	**Yes.**
USSC Multifire GIA Stapler	Not done	Not done	**Non-sterile** (2/6 not sterile)	**No.** Handle failed to return after firing.
EES Endopath ETS	Not done	Not done	**Non-sterile** (2/6 not sterile)	**No.** Handle failed to return after firing.

Conclusions drawn from these investigations are consistent across manufacturer and type of disposable devices. Based on the findings summarized in Table 9 and discussed in greater detail in Section 4.0 of this report, commercial reprocessing of critical single-use medical devices clearly compromises the quality of the device, altering its ability to be used safely and effectively. Moreover, the use of reprocessed disposable devices places patients at unduly high risk of nosocomial infection since the sterility of the reprocessed device cannot be assured.

Virtually all reprocessed single-use devices evaluated for cleanliness in these studies were found to contain dried blood, body fluid, and/or tissue that had not been removed by the cleaning process. This foreign matter could be easily introduced into the next patient upon reuse. Moreover, the internal clearances in some of the devices tested were clogged with residual contamination, possibly restricting the flow of gases necessary to achieve effective sterilization. For certain instruments (e.g., Proximate Linear Cutters) there was evidence suggesting that the cleaning agent used to reprocess the disposable device damaged the device's plastic components. Reprocessing of the sophisticated electromechanical UltraCision Coagulating Shear resulted in changes to key performance characteristics of the instrument, specifically the resonant frequency of the harmonic energy used to cut and coagulate tissue and the force necessary to clamp tissue. Several of the other reprocessed devices had obvious damage, including missing/damaged parts and surface defects, that resulted in the product failing the original manufacturer's product acceptance criteria. There was also considerable evidence of errors associated with the repackaging of reprocessed devices, such as incorrect product identification and notably, the omission of critical information concerning instructions for use.

A key finding of these investigations is that reprocessors' sterilization methods do not adequately provide the required sterility assurance level of one device in a million having a viable organism. In the tests performed by BSC, only 15% of reprocessed biopsy forceps in one series and 20% of those in the other series met the requirements for sterility. These data indicate that approximately 80% of the commercially reprocessed biopsy forceps awaiting reuse on patients in a hospital or medical clinic are **not sterile.** USSC similarly found that almost 20% of the single-use devices subjected to intentional microbial contamination could not be adequately sterilized using a

standard hospital cleaning and EtO resterilization procedure. It should be reemphasized that each of the reprocessed single-use devices that failed sterility testing is categorized as a critical device, intended for direct contact with the bloodstream, tissues, and/or organs. Thus, there is a high risk of nosocomial infection following use of one of these non-sterile reprocessed devices.

6. CONCLUSIONS

Commercial reprocessing of single-use medical devices may compromise the quality of the device, altering its ability to be used safely and effectively. Moreover, the use of reprocessed used disposable devices places patients at an unduly high risk for nosocomial infection since the sterility of the reprocessed device cannot be assured.

7. REFERENCES

1. Gwyne, P. Secondhand woe? The FDA takes a look at refurbished devices; users consider the implications. Materials Management in Health Care, September, 1998.

2. United States Department of Health and Human Services, U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health. *Devices: reuse of medical disposable devices.* In: U.S. Food and Drug Administration. Compliance policy guide 7124.16 §00.500. Rockville (MD): FDA: reissued Sept. 24, 1987.

3. Spaulding EH. Chemical disinfection of medical and surgical materials. In: Laurence CA and Block SS, eds. Disinfection, Sterilization and Preservation, Philadelphia: Lea and Febiger 1968: 517-531.